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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,124	ABRAMS ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21 and 22* is/are allowed.

6)☒ Claim(s) *1,3,5-12 and 17* is/are rejected.

7)☒ Claim(s) *13-16 and 18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 22 is objected to because of the typographical error. Claim 22 recites "within a patient's alimentary cancel" in line 5, appears to read "within a patient's alimentary canal".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view Trudell et al. US 5,207,705.

Mlodozeniec teaches a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments alternatively between sheets (abstract; and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53).

Mlodozeniec does not expressly teach release at two or more different selected sites. However, it is well known in pharmaceutical art that sustained release does provide release rate at various places in the GI tract. To be more specific, see Trudell

for the teaching that sustained release is used to deliver different active compounds at different rates to different sites in the GI tract (column 9, lines 7-18). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Mlodozeniec in view of the teaching of Trudell to obtain the claimed invention, because Trudell teaches a sustained release vehicle is useful to provide any release pattern, and because Mlodozeniec teaches the desirability of formulating a sustained release vehicle.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view Trudell et al. and Lerner et al. US 6,197,331.

Mlodozeniec in view of Trudell are relied upon for the reasons stated above. Mlodozeniec does not explicitly teach an adhesive on an outer surface of the membrane.

Lerner teaches an oral patch composition comprising drug-containing layer, and an adhesive layer (abstract; and column 9, lines 12-67). Lerner further teaches the patch contains multilayer of different drug (column 10, lines 1-16). Thus, it would have been obvious to one of ordinary skill in the art to modify the novel dosage form of Mlodozeniec to contain an adhesive layer in view of the teaching of Lerner, because the use of a patch that contains layers of premeasured dose of drugs, because Lerner teaches the use drug loaded sheets for controlled release of drugs, and because Mlodozeniec teaches a drug loaded web that is advantageous for a wide variety of controlled release oral dosage forms.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view of Trudell et al. and Sanso US 6,350,468.

Mlodozeniec and Trudell are relied upon for the reasons stated above. Mlodozeniec does not teach the combination of drugs in claims 17 and 21.

Sanso teaches a single unit dosage form comprising two different active ingredients being separated from one another by a membrane (see abstract). Combinations of active ingredients include omeprazole and clarithromycine (column 2, lines 15-32; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Mlodozeniec for the combination of omeprazole and clarithromycine to obtain the claimed invention, because Mlodozeniec teaches a novel dosage form for a wide variety of drugs, because Mlodozeniec teaches a novel dosage form that is suitable for combination of two or more incompatible drugs, and because Sanso teaches combination of omeprazole and clarithromycine that is useful in pharmaceutical art.

Claims 1, 3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289, in view of Mlodozeniec et al. US 4,069,084 and Trudell et al.

Sturzenegger teaches a sustained release pharmaceutical dosage form comprising edible web having two or more medicaments electrostatically deposited onto the web that is self destructs or degradable in body fluids or enzymes (see abstract, columns 6-8, and columns 24-26). Before the deposit of the medicaments, the web can

be coated with an adhesive layer (column 17, lines 5-41). The web can be processed into separate tablet layers, capsules, dragees, or suppositories (column 3, lines 38-41; and column 4, lines 58-60).

Sturzenegger does not expressly teach the fixed unit dose quantities of the medicaments.

Mlodozeniec teaches a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments alternatively between sheets (abstract; and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Sturzenegger to contain a fixed unit dose of drugs in view of the teaching of Mlodozeniec, because Sturzenegger teaches the exact and uniform deposition of the active ingredient on the web (column 11, lines 1-5), because Sturzenegger teaches the amount of active ingredient loaded can be determined by transmission spectrophotometry (column 12, lines 46-56), because Sturzenegger teaches the advantageous results of a single dosage form containing two or more medicaments being separated by edible membrane, and because Mlodozeniec teaches a novel dosage form containing edible web having deposited thereon a fixed dose of active ingredients that exhibits many advantageous results over the conventional dosage forms (columns 3-4).

It is noted that Sturzenegger does not expressly teach release at two or more different selected sites. However, it is well known in pharmaceutical art that sustained release does provide release rate at various places in the GI tract. To be more specific, see Trudell for the teaching that sustained release is used to deliver different active compounds at different rates to different sites in the GI tract (column 9, lines 7-18). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Sturzenegger in view of the teaching of Trudell to obtain the claimed invention, because Trudell teaches a sustained release vehicle is useful to provide any release pattern, and because Sturzenegger teaches the desirability of formulating a sustained release vehicle suitable for delivery two or more different active compounds.

Claims Allowable

Claims 13-16 and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21 and 22 are allowed.

Response to Arguments

Applicant's arguments filed 11/21/06 have been fully considered but they are not persuasive.

Applicant argues that the rejections are believed to be in error because they include claim 4, which was cancelled in the previous amendment and incorporated into the independent claims.

In response to applicant's argument, the number "4" in the rejections has been deleted to correct the typographical error.

Applicant argues that Mlodozeniec teaches a sustained release that provides release relative to time, whereas the claimed invention claimed a controlled release that provides release to two or more selected sites within a patient alimentary canal.

However, in response to applicant's argument, it is well known in pharmaceutical art that sustained release can be use to provide release of two or more active compounds to various places in the GI tract (see for example Roche US 5,075,114 at column 5, lines 25-27; and Trudell et al. US 5,207,705 at column 9, lines 7-18).

Applicant argues that Santo does not teach site-specific delivery, at two or more sites within the alimentary canals as required by claim 1.

In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Santo is relied upon solely for the teaching that combination of omeprazole and clarithromycine is well known in the art.

Applicant argues that Sturzenegger like Mlodozeniec, teaches a sustained release formulation, but fails to teach site-specific delivery along two or more selected sites within a patient alimentary canal.

However, in response to applicant's argument, Sturzenegger is cited in combination with Trudell for the teaching sustained release vehicle can be use to provide release of two or more active compounds to various places in the GI tract (Trudell et al. US 5,207,705 at column 9, lines 7-18).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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